

(d) It is incumbent upon contractor to ensure that continuing IRB review approval occurs in accordance with 15 CFR part 27. In the event that continuing review approval does not occur as set forth by 15 CFR part 27, contractor is to notify the Contracting Officer immediately.

(e) Contractor must report all adverse events to the cognizant IRB and to the Contracting Officer. In the event that adverse events are reported to the cognizant IRB and the Contracting Officer, the Government may suspend this contract pending a full review of the adverse event by the cognizant IRB.

(f) If the conditions upon which IRB approval is based should change in any way, contractor shall immediately notify the Contracting Officer, in writing, of the specified change.

(g) Failure to comply with this contract clause will be considered material non-compliance with the contract, and the Contracting Officer may take appropriate enforcement action, including disallowing costs, suspension or termination of the contract.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

1352.235-73 Research involving human subjects—after initial contract award.

As prescribed in 48 CFR 1335.006(d), insert the following clause:

**RESEARCH INVOLVING HUMAN SUBJECTS—
AFTER INITIAL CONTRACT AWARD (APR 2010)**

(a) No research involving human subjects is currently included in this contract/task order, and no research involving human subjects is permitted under this contract/task order unless expressly authorized, in writing, by the Contracting Officer.

(b) The Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by the Department of Commerce at 15 CFR part 27, requires that contractors maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a “human subject” as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term “research” means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(c) The Common Rule also sets forth categories of research that may be considered

exempt from this policy. These categories are specified at 15 CFR 27.101(b).

(d) In the event that human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR part 46 subparts B, C and D, as appropriate, for the protection of members of a protected class.

(e) Should research involving human subjects become necessary for carrying out this contract/task order, prior to undertaking or conducting such human subjects research, contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board (“cognizant IRB”). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB is registered with the United States Department of Health and Human Services’ Office for Human Research Protections (“OHRP”);

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by the OHRP.

(f) Prior to starting any research involving human subjects, contractor shall submit appropriate documentation to the Contracting Officer for Government institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, advertisements, recruitment material, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, advertisements, recruitment material, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [Note: this option is not available for activities that fall under 45 CFR part 46 subpart C].

(g) In addition, if contractor modifies a human subjects research protocol, advertisement, recruitment material, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for Agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

(h) No work involving human subjects may be undertaken, conducted, or costs incurred

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and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

1352.237-70 Security processing requirements—high or moderate risk contracts.

As prescribed in 48 CFR 1337.110-70 (b), insert the following clause:

SECURITY PROCESSING REQUIREMENTS—HIGH OR MODERATE RISK CONTRACTS (APR 2010)

(a) Investigative Requirements for High and Moderate Risk Contracts. All contractor (and subcontractor) personnel proposed to be employed under a High or Moderate Risk contract shall undergo security processing by the Department's Office of Security before being eligible to work on the premises of any Department of Commerce owned, leased, or controlled facility in the United States or overseas, or to obtain access to a Department of Commerce IT system. All Department of Commerce security processing pertinent to this contract will be conducted at no cost to the contractor. The level of contract risk will determine the type and scope of such processing, as noted below.

(1) Investigative requirements for Non-IT Service Contracts are:

(i) High Risk—Background Investigation (BI).

(ii) Moderate Risk—Moderate Background Investigation (MBI).

(2) Investigative requirements for IT Service Contracts are:

(i) High Risk IT—Background Investigation (BI).

(ii) Moderate Risk IT—Background Investigation (BI).

(b) In addition to the investigations noted above, non-U.S. citizens must have a pre-appointment check that includes an Immigration and Customs Enforcement agency check.

(c) Additional Requirements for Foreign Nationals (Non-U.S. Citizens). To be employed under this contract within the United States, non-U.S. citizens must have:

(1) Official legal status in the United States;

(2) Continuously resided in the United States for the last two years; and

(3) Obtained advance approval from the servicing Security Officer of the contracting operating unit in consultation with the DOC Office of Security (OSY) headquarters. (OSY routinely consults with appropriate agencies regarding the use of non-U.S. citizens on contracts and can provide up-to-date information concerning this matter.)

(d) Security Processing Requirement. Processing requirements for High and Moderate Risk Contracts are as follows:

(1) The contractor must complete and submit the following forms to the Contracting Officer's Representative (COR):

(i) Standard Form 85P (SF-85P), Questionnaire for Public Trust Positions;

(ii) FD-258, Fingerprint Chart with OPM's designation in the ORI Block; and

(iii) Credit Release Authorization.

(2) The Sponsor will ensure that these forms have been properly completed, initiate the CD-254, Contract Security Classification Specification, and forward the documents to the cognizant Security Officer.

(3) Upon completion of security processing, the Office of Security, through the servicing Security Officer and the Sponsor, will notify the contractor in writing of an individual's eligibility to be provided access to a Department of Commerce facility or Department of Commerce IT system.

(4) Security processing shall consist of limited personal background inquiries pertaining to verification of name, physical description, marital status, present and former residences, education, employment history, criminal record, personal references, medical fitness, fingerprint classification, and other pertinent information. For non-U.S. citizens, the Sponsor must request an Immigration and Customs Enforcement agency check. It is the option of the Office of Security to repeat the security processing on any contract employee at its discretion.

(e) Notification of Disqualifying Information. If the Office of Security receives disqualifying information on a contract employee, the COR will be notified. The Sponsor, in coordination with the Contracting Officer, will immediately remove the contract employee from duties requiring access to Departmental facilities or IT systems. Contract employees may be barred from working on the premises of a facility for any of the following:

(1) Conviction of a felony crime of violence or of a misdemeanor involving moral turpitude;

(2) Falsification of information entered on security screening forms or on other documents submitted to the Department;

(3) Improper conduct once performing on the contract, including criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct prejudicial to the Government, regardless of whether the conduct was directly related to the contract;

(4) Any behavior judged to pose a potential threat to Departmental information systems, personnel, property, or other assets.

(f) Failure to comply with security processing requirements may result in termination of the contract or removal of contract employees from Department of Commerce facilities or denial of access to IT systems.